Clinical Trial Diversity Action Plan Development Checklist

Get Started on Your Clinical Trial Diversity Action Planning Now

Clinical trials should enroll patients that are representative of the population that a drug is intended to serve to accurately reflect the effectiveness and adverse event outcomes in a variety of product users. Over the last decade, the FDA has taken steps toward improving diversity in clinical trials. The most recent Draft Guidance[1] provides new details to sponsors. Even though the guidance will not be finalized for some time, sponsors should begin to comply with the Draft Guidance as soon as possible.

UBC has assembled this checklist of considerations to help you develop your clinical trial diversity action plan (DAP).

Know the Requirement

UNDERSTAND WHEN A DAP IS REQUIRED

- ☐ Requirements for drugs
- ☐ Requirements for devices
- ☐ Guidance for rare diseases, global/multiple studies
- ☐ Waivers

UNDERSTAND THE PROCESS

- ☐ When should planning start?
- ☐ When will DAPs need to be submitted?
- ☐ What are the format requirements?
- ☐ What are the reporting requirements?

UNDERSTAND THE DAP SCOPE

- ☐ Race, ethnicity, age group, sex
- ☐ Geographic location, socioeconomic status
- ☐ Gender identity, sexual orientation
- ☐ Physical and mental disabilities
- ☐ Pregnancy status, lactation status
- ☐ Comorbidities

UNDERSTAND WHAT IS NEEDED FOR RATIONALE

- ☐ Demographic characteristics
- ☐ Disease prevalence and incidence
- ☐ Pharmacokinetics
- ☐ Clinical characteristics
- ☐ Access to care
- ☐ Differences in safety and effectiveness
- ☐ Outcomes with other therapies, standard of care

Know the Patient Population

UNDERSTAND THE PATIENT

- ☐ Barriers to participation
- ☐ Care giver / Care partner involvement
- ☐ Demographic characteristics that inform education, outreach, and recruitment

UNDERSTAND THE PATIENT JOURNEY

- ☐ Disease prevalence and incidence
- ☐ Disease natural history
- ☐ Diagnosis and treatment journey
- ☐ Access to care

UNDERSTAND THE DISEASE

- ☐ Indication
- ☐ Pathophysiology, biomarkers
- ☐ Prevention and screening strategies
- ☐ Diagnostic strategies
- ☐ Available treatments
- ☐ Comorbidities

UNDERSTAND AVAILABLE METHODS

- ☐ Incorporate the patient voice
- ☐ Collaborate with patient organizations
- ☐ Review existing literature
- ☐ Use RWD to identify relevant HCPs and sites
- ☐ Use RWD for targeted patient geolocation
- ☐ Tailor outreach based on patient population
- ☐ Establish metrics and KPIs

UBC combines a depth of experience in patient advocacy and recruitment, epidemiology, clinical operations, late-phase and real-world study design and execution, and strategic planning. Connect with us today to learn more.

[1]Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies, Draft Guidance for Industry, JUNE 2024. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/diversity-action-plans-improve-enrollment-participants-underrepresented-populations-clinical-studies

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